

REMARKS

The Official Action of December 16, 2009 withdrew all the rejections set out in prior Office Actions, but noted the need for correction of the list of co-pending applications and objected to claims 19, 28, and 31-35 for certain informalities as noted on page 2 of the Action. The Action also rejected claims 19, 24, 25, and 35 under 35 U.S.C. 102 as being anticipated by the Pisharodi '926 patent. Claims 19 and 24-27 were rejected under §102(b) as being anticipated by the Perren, *et al.* patent ("Perren"). Claims 2 and 28-34 were rejected under 35 U.S.C. 103 as being obvious over the combination of the Pisharodi '926 patent in view of either the Steffee '514 or Pisharodi '762 patents and claims 20-21 were rejected under that same section of the Statute as being obvious over the combination of those same three patents and Muhanna. Claims 22-23 were rejected under §103 over the combination of those same four patents and the Haldiman '576 patent. Applicant respectfully traverses all the objections/rejections set out in the December 16, 2009 Action, and in accordance with the requirements of 37 C.F.R. 1.111(b), the basis for traversing these rejections is set out below.

The list of co-pending applications was canceled from the specification in Applicant's Response to Official Action of June 29, 2005. If there are unresolved issues relating to this matter, Applicant is ready and willing to attend to them and respectfully requests a bit of explanation so that they can be addressed.

With respect to the objection to claims 19, 28, and 31-35, Applicant re-asserts the remarks and arguments set out in Applicant's Response to Official Action of November 19, 2008 (please note the typographical error in the title of that filing, which should have referred to a November 19, 2007 Official Action) and Response to Official Action of March 19, 2009 as if fully set forth in this Response. Specifically, Applicant calls attention to the fact that claims 19, 28, and 31-35 are all method claims. In the absence of prior art that requires Applicant to amend claims 19, 28, and 31-35 to define a patentable invention or a §112 rejection based on the allegedly "confusing" recitation of terms such as "resisting," "biasing," and "maintaining," it is entirely appropriate for Applicant to define the invention as a method including these steps. Reconsideration and withdrawal of this objection to claims 19, 28, and 31-35 is again respectfully requested.

Applicant appreciates the clarification of the §102 rejection of claim 19 over Pisharodi '926 set out on page 7 of the Action. However, the claim recites the step of "inserting an elongate implant" into the space from which a portion of the intervertebral disk has been removed, and there is no disclosure of an elongate implant in Pisharodi '926. To the contrary, the implant disclosed in Pisharodi '926 is clearly shown as being "saucer-shaped," not elongate.

As previously noted (*see* pages 6-7 Applicant's Response to Official Action of March 19, 2009), a disk prosthesis as described in Pisharodi '926 is not an implant such as the implant described and claimed in the captioned application and as also previously noted, the entire disk is removed before the implant described in Pisharodi '926 is inserted instead of the portion of the disk that is recited in claim 19. Without regard to these distinctions, however, the structure of the prosthesis 2 of the '926 patent is different than the structure of the implant recited in claim 19, and that difference is reflected in the recitation of the steps of the method recited in claim 19 (the claim recites, for instance, that the insert is released **after** the implant has been inserted into the disk space and rotated). Applicant has amended claim 19, but not for the purpose of defining over Pisharodi '926; the amendment was instead made for the purpose of completing the steps of the method (specifically, once the implant is inserted, it is rotated and the insert is then released to bias against the adjacent vertebra, the rotation step having been inadvertently omitted). Claims 24, 25, and 35 are all dependent on claim 19 and are all likewise allowable as being dependent on allowable main claim. In addition, Applicant re-asserts the remarks set out on page 7 of the Response to Official Action of March 19, 2009 calling attention to the distinction between the disk prosthesis disclosed in Pisharodi '926 and the implant of the present invention. Reconsideration and withdrawal of the rejection of claims 19, 24, 25, and 35 over the Pisharodi '926 patent is respectfully requested.

The additional explanation of the §102 rejection of claims 19 and 24-27 over the Perren patent is also helpful. However, the new reference cited in support of the allegation that the connecting means 4 of Perren "biases" the plates 1 apart from each other does not change Applicant's assessment of that rejection such that the rejection is again traversed. Regardless of the disclosure of the Flomenbilt patent, Perren describes only a first relative position of the plates 1 that is of smaller volume for introduction into the disk space and a second relative position of the plates 1 of a "more voluminous configuration as shown in Fig. 3 which is designed to provide optimal spacing function for the two adjacent vertebrae" (quoting from col. 3, lines 28-30 of Perren). Clearly Perren discloses only that the two plates are either held a first, shorter distance apart or a second, "more voluminous" distance apart without any disclosure of any intermediate position or spring function of the connecting means 4. In this regard, it appears that the Perren patent is inconsistent with the description of the properties of SMA materials set out in Flomenbilt, and as long as Perren is inconsistent with another reference and/or be lacking in definiteness, it is respectfully urged that Perren does not support a §102 rejection of claim 19.

Applicant notes the explanation of the allegation that the Perren prosthetic disk is elongate, but as specifically noted on page 4 of the Office Action, the drawings of Perren are not

to scale such that it can only be argued that the device disclosed in that reference is elongate. Further, although added so as to completely recite the method steps of Applicant's claimed invention (and not to define over Perren or Pisharodi '926), the newly recited rotation step helps clarify how the present invention differs from Perren. Because that device is only arguably elongate and therefore only arguably has a longitudinal axis about which it can be rotated, Perren does not disclose releasing an insert after rotation (as previously noted, Perren does not even disclose an insert as claimed), nor does it disclose that rotation is resisted as recited in the last step of the method claimed in claim 19. Reconsideration and withdrawal of the §102 rejection of claim 19 over Perren is respectfully requested in light of these several differences between the device disclosed in that patent and the method of claim 19.

Claims 24-27, also rejected under §102 over Perren, are allowable simply because they depend upon an allowable main claim. However, each of claims 24-27 recite method steps that are not disclosed in Perren and so each claim is also allowable on its own merits. As Applicant previously noted, there is no disclosure in Perren of a spring for biasing as called out in claim 24. There is no disclosure in Perren of restraining the two plates 1 against relative movement until after the implant is rotated in the disk space as recited in claim 25. There is no disclosure in Perren of anything that is springy and compressible as recited in claim 26. Reconsideration and withdrawal of the §102 rejection of claims 19 and 24-27 over Perren is respectfully requested in light of these differences between Perren and the claimed invention.

Turning now to the §103 rejection of claims 2 and 28-34 over Pisharodi '926 in view of Steffee or Pisharodi '762, Applicant certainly agrees that Pisharodi '926 fails to disclose the step of rotating the implant after insertion. Applicant does not agree, however, that one skilled in the art would re-orient that device as taught by Pisharodi '762 or Steffee for the same reason noted above. Specifically, Pisharodi '926 discloses a device that replaces the intervertebral disk whereas both Steffee and Pisharodi '762 describe devices inserted into the space from which a portion of the intervertebral disk has been removed and then rotated once inserted into that space. Because of this difference, and contrary to the allegation that it would have been obvious to re-orient the Pisharodi '926 device because of the teaching of re-orienting set out in Steffee and/or Pisharodi '762, those skilled in the art would actually assert that one would **not** re-orient the Pisharodi '926 device. Reconsideration and withdrawal of the §103 rejection of claim 2 is therefore requested.

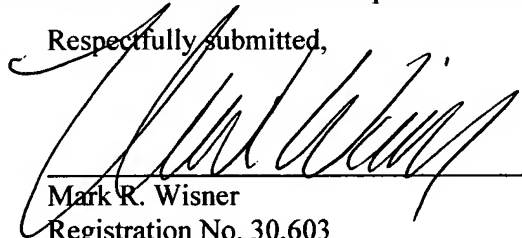
Each of claims 28-34, directly or indirectly dependent on claim 2, are allowable because they depend from an allowable main claim. With the possible exception of claim 33, each also recites additional method steps that is/are not disclosed in the cited references. None of the

references teach restraining an insert against movement until after the implant is inserted into a space from which a portion of the intervertebral disk has been removed as recited in claim 28. None discloses a compressible insert as recited in claim 29 (indeed, it is argued elsewhere in the Action that the insert is incompressible). The grammar/syntax of the comments about claim 30 at the bottom of page 5 of the Action are such that Applicant is uncertain of the basis for that rejection. However, claim 30 depends from claim 29, which recites that the implant is comprised of relatively incompressible material and such a material cannot be assembled into the form shown in Fig. 2 of Pisharodi '926 as alleged in the Action. There is no suggestion in the cited references whatsoever of maintaining alignment as recited in claim 31 and, as set out above, there would be no reason to resist rotation of the implant disclosed in Pisharodi '926, regardless of the teachings of Steffee or Pisharodi '762 such that the rejection of claim 32 is inappropriate in light of this prior art. Similarly, there is no need to resist movement of the device disclosed in Pisharodi '962 out of the disk space such that the rejection of claim 34 is inappropriate. Reconsideration and withdrawal of the rejection of claims 28-34 is respectfully requested.

Muhanna does not add anything to the combination of Pisharodi '926, Steffee, and Pisharodi '762 that overcomes the deficiencies in the rejection of claims 20-21. Applicant does wonder how those references are relevant to a rejection of claims 20-21, which are dependent on claim 19, "as applied to claims 2 and 28-34" (quoting from the second line of page 6 of the Action), but the bottom line is that no *prima facie* showing of the obviousness of claim 19 has been established such that claims 20-21 are allowable because they depend from an allowable main claim. Claims 22-23 likewise depend from claim 19 and are therefore also allowable.

Entry of the above amendments, consideration of the remarks set out herein, allowance of the claims, and passage of the application to issuance are all respectfully requested. In the event there are questions and/or issues yet to be answered in this application, it is respectfully requested that Applicant's Attorney be contacted at the address and phone number set out below.

Respectfully submitted,



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